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Sam Brownback, Governor

**Drug Utilization Review Board
Meeting Agenda, Open Session
October 9, 2013, 10:00 a.m.-2:00 p.m.**

Meeting Location

HP Enterprise Services, Capital Room
6700 SW Topeka Blvd, Bldg. 283 J, Topeka, KS 66619

Board Members

Tim Heston, DO	Daniel Sutherland, RPh
John Kollhoff, PharmD	Kevin Waite, PharmD
Judy McDaniel Dowd, PA-C	Roger Unruh, DO

KDHE-DHCF Staff

Brandy Allen	Katy Brown, PharmD
Kelley Melton, PharmD	

HP Enterprise Services/HID Staff

Nicole Ellermeier, PharmD	Karen Kluczykowski, RPh
Nancy Perry, RN	

MCO Staff

Thomas Kaye, RPh, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of July 10, 2013 Meeting Minutes

III. NEW BUSINESS

A. New Preferred Drug List (PDL) Class

1. Hepatitis C Protease Inhibitors

In September 2013, the PDL Committee approved the addition of "Hepatitis C Protease Inhibitors" to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Urologics: Beta-3 Adrenergic Agonists

In September 2013, the PDL Committee approved the addition of “Urologics: Beta-3 Adrenergic Agonists” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

In September 2013, the PDL Committee approved the addition of “SGLT2 Inhibitors” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. Oral Multiple Sclerosis Agents

In September 2013, the PDL Committee approved the addition of “Oral Multiple Sclerosis Agents” to the PDL. Prior authorization criteria to allow patients access to non-preferred agents are being proposed. The criteria are consistent with all other classes on the PDL.

- i. Non-Preferred PDL Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

B. Prior Authorization Criteria Revisions

1. Buprenorphine for Opioid Dependence (Suboxone® & Zubsolv® (buprenorphine/naloxone), & Subutex® (buprenorphine))

In July 2013, the U.S. Food and Drug Administration (FDA) approved Zubsolv for the maintenance treatment of opioid dependence. Revised prior authorization criteria are being proposed to include this new agent.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. Xyrem® (sodium oxybate)

Xyrem is a central nervous system depressant indicated for the treatment of cataplexy in narcolepsy and excessive daytime sleepiness in narcolepsy. In July 2009, the DUR Board approved prior authorization criteria for Xyrem requiring the Pharmacy Program Manager review all prior authorizations. Revised prior authorization criteria are being proposed to ensure appropriate utilization based upon the FDA-approved indications.

- i. Revised Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

C. New Prior Authorization Criteria

1. **Xgeva® (denosumab)**

Xgeva has the same active ingredient as Prolia®, which has approved prior authorization criteria. Xgeva is being proposed for prior authorization criteria to remain consistent among denosumab products. Xgeva is approved for the prevention of skeletal-related events in patients with bone metastases from solid tumors, and the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. Prior authorization criteria are being proposed based upon FDA-approved indications.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

2. **Ravicti® (glycerol phenylbutyrate)**

Ravicti is indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) that cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

3. **Buphenyl® (sodium phenylbutyrate)**

Buphenyl is indicated as adjunctive therapy in the chronic management of patients with UCDs. Buphenyl must be combined with dietary protein restriction and, in some cases, essential amino acid supplementation. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

4. **Diclegis® (doxylamine succinate/pyridoxine hydrochloride)**

Diclegis is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog. It is indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

5. **Osphena® (ospemifene)**

Osphena is an estrogen agonist/antagonist indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy due to menopause. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

6. Prialt® (ziconotide Intrathecal infusion)

Prialt is an intrathecal infusion N-type calcium channel antagonist indicated for the management of severe chronic pain in patients for whom Intrathecal therapy is warranted, and who are intolerant or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or Intrathecal morphine. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

7. Benlysta® (belimumab)

Benlysta is a B-lymphocyte stimulator-specific inhibitor indicated for the treatment of adults with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

8. Soliris® (eculizumab)

Soliris is a complement inhibitor indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria to reduce hemolysis, and the treatment of patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

9. Bivigam® (immune globulin intravenous (human))

Bivigam is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

10. Carimune® NF (immune globulin intravenous (human))

Carimune NF is an immune globulin indicated for the maintenance treatment of patients with primary immunodeficiencies, and the treatment of acute or chronic immune thrombocytopenic purpura. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

11. Flebogamma® (immune globulin intravenous (human))

Flebogamma is an immune globulin indicated for the treatment of primary immune deficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

12. Octagam® (immune globulin intravenous (human))

Octagam is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

13. Privigen® (immune globulin intravenous (human))

Privigen is an immune globulin indicated for the treatment of primary humoral immunodeficiency, and chronic immune thrombocytopenic purpura. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

14. Gammaplex® (immune globulin intravenous (human))

Gammaplex is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

15. Gammagard® S/D (immune globulin intravenous (human))

Gammagard S/D is an immune globulin indicated for the treatment of primary immunodeficiency, prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia, prevention and/or control of bleeding in Chronic Idiopathic Thrombocytopenia Purpura, and prevention of coronary artery aneurysms associated with Kawasaki syndrome. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

16. Gammagard® Liquid (immune globulin infusion (human))

Gammagard liquid is an immune globulin indicated as replacement therapy for primary humoral immunodeficiency, and as maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

17. Gammaked® (immune globulin injection (human))

Gammaked is an immune globulin indicated for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

18. Gamunex®-C (immune globulin injection (human))

Gamunex-C is an immune globulin indicated for the treatment of primary humoral immunodeficiency, idiopathic thrombocytopenic purpura, and chronic inflammatory demyelinating polyneuropathy. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

19. Hizentra® (immune globulin subcutaneous (human))

Hizentra is an immune globulin indicated for the treatment of primary immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

20. Vivaglobin® (immune globulin subcutaneous (human))

Vivaglobin is an immune globulin indicated for the treatment of primary humoral immunodeficiency. Prior authorization criteria are being proposed to ensure appropriate use based on FDA-approved labeling information.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

21. Mekinist® (trametinib)

Mekinist is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic mutations approved by the FDA.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

22. Tafinlar® (dabrafenib)

Tafinlar is a kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic mutations approved by the FDA.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

23. Herceptin® (trastuzumab)

Herceptin is a Human Epidermal Growth Factor Receptor 2 (HER2) antagonist indicated for the treatment of HER2 overexpressing breast cancer, and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. Prior authorization criteria are being proposed to ensure appropriate use based on the specific genetic marker approved by the FDA.

- i. Prior Authorization Criteria
- ii. *Public Comment
- iii. Board Discussion

D. Miscellaneous Items

1. Kansas Medical Assistance Program (KMAP) State Fiscal Year 2013 (SFY 2013) Program Assessment

Health Information Designs, LLC (HID) will present the SFY 2013 program assessment for KMAP.

- i. Program Assessment
- ii. *Public Comment
- iii. Board Discussion

2. Retrospective Drug Utilization Review Intervention Topic Selections

Each year Health Information Designs, LLC performs 5 retrospective DUR interventions for the fee-for-service population. For the state fiscal year 2014, the DUR Board needs to select the final two topics for intervention.

- i. Intervention Topics
- ii. *Public Comment
- iii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

**Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for January 8, 2014.**

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion.
Informal comments will be accepted from members of the audience at various points in the agenda.

****THIS AGENDA IS SUBJECT TO CHANGE****